



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Immvac, Inc.
USDA Vet Biologics Establishment Number	345
Product Code	7910.01
True Name	Salmonella Typhimurium Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ENDOVAC-Beef with Immune Plus - Endovac Animal Health LLC ENDOVAC-Dairy with Immune Plus - Endovac Animal Health LLC ENDOVAC-Porci with Immune Plus - Endovac Animal Health LLC Endovac-Bovi - No distributor specified
Date of Compilation Summary	November 02, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	Salmonella Typhimurium
Study Purpose	To demonstrate efficacy against <i>E. Coli</i> Clinical Coliform Mastitis
Product Administration	Cows: one dose at or shortly after dry-off and repeat 2-3 weeks prior to calving Heifers: one dose during the last trimester of pregnancy and repeat approximately 3 weeks prior to calving
Study Animals	Cows and heifers
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	July 29, 1993

Study Type	Efficacy
Pertaining to	Escherichia coli and Pasteurella multocida
Study Purpose	To demonstrate efficacy against the effects of endotoxemia in cattle due to Pasteurella endotoxins and Escherichia coli 055:B5.
Product Administration	IM
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	May 19, 1988

Study Type	Efficacy
Pertaining to	Salmonella typhimurium and Mannheimia haemolytica (Pasteurella haemolytica)
Study Purpose	To demonstrate efficacy against the effects of endotoxemia in cattle due to <i>Salmonella typhimurium</i> and <i>Mannheimia haemolytica</i> (<i>Pasteurella haemolytica</i>).
Product Administration	IM
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 18, 1994

Study Type	Efficacy
Pertaining to	Salmonella typhimurium and Salmonella choleraesuis
Study Purpose	To demonstrate efficacy against endotoxin-mediated diseases in pigs caused by <i>Salmonella typhimurium</i> and <i>Salmonella choleraesuis</i>
Product Administration	IM
Study Animals	Swine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 31, 1992

Study Type	Safety
Pertaining to	All
Study Purpose	Safety under typical field conditions
Product Administration	IM
Study Animals	Cattle including cows in dry period and cattle during the last trimester of pregnancy
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	October 16, 1990

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Intramuscular in swine
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	January 31, 1992